

Breakfast: tea or coffee in any quantity without sugar. Only one tablespoonful of milk allowed in 24 hr. Saccharin or other sweeteners could be used.

Lunch: 100 grams. of veal, beef, chicken breast, fresh white fish, lobster, crab or shrimp. All visible fat was carefully removed before cooking, and the meat weighed raw. Salmon, tuna fish, herring, dried or pickled fish was not allowed.

The chicken breast was removed raw from the bird. One type of vegetable could be only chosen from the following: spinach, chard, chicory, beet-greens, green salad, tomatoes, celery, fennel, onions, red radishes, cucumbers, asparagus, and cabbage. One breadstick (grissini) or one Melba toast was allowed, and an apple or an orange, or a handful of strawberries or one-half grapefruit.

For dinner: The same four choices as lunch.

The juice of only one lemon daily was allowed for all purposes. Salt, pepper, vinegar, mustard powder, garlic, sweet basil, parsley, thyme, marjoram, etc., could be used for seasoning, but no oil, butter or dressing. Tea, coffee, plain water, mineral water were the only drinks allowed, but they could be taken in any quantity and at all times.

Clinicometric controls

Volunteers assisted twice weekly at the clinic to be controlled and weighed. The following evaluations were completed once a week:

I. Height and Weight, performed on a medical scale. Volunteers were weighed using normal underwear.

II. Body circumferences. Using a flexible, non elastic metric tape, the following anatomic areas were assessed:

- Wrist (WRT), at the level of flexion fold (wrist-forearm);
- Breast (BRE), submammary fold;
- Waist (WAT): at the hypogastric region level;
- Abdominal (ABD), at the navel level;
- Hips (HIP): pubic line;
- Thighs (THI): 8 cm. below pubic line;
- Suprapatellar (ROT), at the patella upper border;
- Ankle (ANK), at the flexion fold (peroneal protuberance).

III. Skinfold thickness. Using a Lange Skinfold Caliper (Cambridge Scientific Industries, Cambridge, Maryland), the following folds were examined:

- Tricipital (TRI), arm midline, posterior region and tricipital muscle zone;
- Anterior Axilar line (AXA), at the fold created when pinching the skin region at the level of the pectoralis muscle extending to the arm;
- Subscapular (SCA (i)): inferior scapular spine;
- Thoracic (TOR): at the fold created when pinching the region located immediately below the ribs, at the level of an imaginary line extending from anterior axilar line;
- Suprailiac (ILI), at the fold created 4 cm above the anterior superior iliac spine;
- Supraumbilical (UMB(u)), 3 cm above navel;
- Infraumbilical (UMB(i)), 3 cm below navel;
- Thighs (THI), internal aspect of thighs, eight cm below the pubic area;
- Patellar area (ROT), at the fold created when pinching the region located 6 cm medial to the internal patellar border.

IV. Bioelectrical impedance. Using Tetrapolar Bioelectrical Impedance (TBI) with a body fat analyzer Maltron, model BF-905 (Maltron International Ltd., Rayleigh, Essex).

Volunteers voided previous to the evaluation, placed on supine position, and allowed to rest half an hour before determination. Self-adhering electrodes were placed on extremities. Every determination was performed with a separate set of electrodes, discarded after single use.

The following TBI determinations were assessed:

1. Fat weight (FW)
2. Lean weight (LW)
3. Water weight (WW)
4. Calories (CAL)

V. β -hCG determinations: all subjects enrolled in the trial were studied for plasmatic β -hCG levels by an ELISA test (64) on 0-15-30 study days.

VI. Mood questionnaire: from the first study week on, patients were given weekly self-administered questionnaires to be completed at home. It consisted of twenty-four questions related to their mood changes in the course of the study, plus four questions related to adverse drug effects. They returned the data at the time of the subsequent visit to the clinic.

(Continued on page 201)